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IX. Summary of Safety and Effectiveness

K012539

SUBMITTER:	United States Surgical A division of Tyco Healthcare Group, LP 150 Glover Avenue Norwalk, CT 06856
CONTACT PERSON:	Chester McCoy
DATE PREPARED:	August 3, 2001
CLASSIFICATION NAME:	Dilator (Other)
COMMON NAME:	Percutaneous Dilator with Sheath
PROPRIETARY NAME:	VersaStep*
PREDICATE DEVICES:	InnerDyne Step Trocar Expandable Port, "One-Step*" (K961940) Auto Suture* Modified Versaport* Trocar (K954108)
DEVICE DESCRIPTION:	The VersaStep* single use system consists of a sterile insufflation and access needle, a radially expandable sleeve, and a dilator/ cannula. The cannula and dilators are available in 5 mm, 5 mm – 11 mm, and 5 mm – 12 mm diameters.
INTENDED USE:	The VersaStep* single use system is intended to provide dilation access to the abdominal and thoracic cavities for performing diagnostic and operative abdominal and thoracic procedures. The VersaStep* single use system is indicated for the following uses: ▪ Laparoscopic access to the abdominal cavity, both primary and secondary punctures ▪ Thoracoscopic access to the thoracic cavity, both primary and secondary punctures
MATERIALS:	All component materials of the VersaStep* single use system are comprised of materials which are in accordance with ISO Standard # 10993-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Chester McCoy
Program Manager, Regulatory Affairs
United States Surgical
A Division of Tyco Healthcare Group, LP
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K012539
Trade/Device Name: VersaStep
Regulation Number: 870.1390
Regulatory Class: II
Product Code: GCJ
Dated: August 6, 2001
Received: August 7, 2001

Dear Mr. McCoy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Indications for Use

510(k) Number (if known): K 012539

Device Name: VersaStep*

Indications For Use:

The VersaStep* single use system is intended to provide dilation access to the abdominal and thoracic cavities for performing diagnostic and operative abdominal and thoracic procedures. The VersaStep* single use system is indicated for the following uses:

- Laparoscopic access to the abdominal cavity, both primary and secondary punctures
- Thoracoscopic access to the thoracic cavity, both primary and secondary punctures

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use:
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012539